EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

September 23, 2019

Sent By Email
John C. Bostic
Assistant United States Attorney
Northern District of California
150 Almaden Boulevard, Suite 900
San Jose, California 95113
John.Bostic@usdoj.gov

Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Mr. Bostic:

This letter responds to the Court's July 19, 2019 Order in the above-captioned action instructing the Centers for Medicare & Medicaid Services (CMS) to advise the Prosecution no later than September 23, 2019 whether the agency anticipates completing its production of all documents responsive to the six categories of documents described in that Order by the October 2, 2019 deadline.

CMS anticipates producing all documents responsive to the six categories that are not protected by the attorney-client or work product privileges by the deadline or shortly thereafter. Specifically, CMS produced a total of 2,688 responsive documents to the parties on July 31, 2019 and September 20, 2019. In addition, CMS collected the remaining responsive documents, completed its attorney-client privilege review, and submitted a request to DOJ's Litigation Technology Service Center (LTSC) today to prepare those documents for production. The agency anticipates that this production will include 11,200 responsive documents. The LTSC has not yet provided an estimate of when the production will be ready, but these requests typically take approximately ten work days to prepare. CMS will provide you with an estimated production date as soon as we hear from the LTSC.

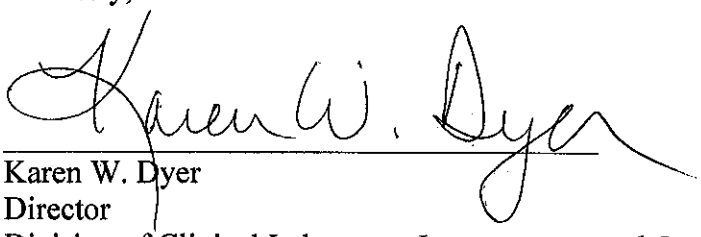
To identify documents responsive to the six categories, CMS used the time period September 1, 2013 through December 31, 2016. This time period was proposed, and agreed to, by Mr. Balwani's counsel to narrow the time period relevant to Mr. Balwani's subpoena to CMS in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. The agency determined that this time period reasonably captured all CMS documents responsive to the six categories at issue in the criminal case. All of the key events occurred within this period. For example, Theranos's application for CLIA certification (CMS Form 116) was signed by the Theranos laboratory director on November 24, 2013 and the first CLIA survey of a Theranos laboratory was conducted by the California Department of Public Health, Laboratory Field Services on December 3, 2013. The CMS 2567 Statement of Deficiencies and Plan of Correction was issued the same day. Further supporting this time period limitation, Theranos notified CMS on October 5, 2016 that it had decided to close the Newark, California and Scottsdale, Arizona laboratories and surrender its CLIA certifications.

As previously explained, CMS does not have documents responsive to Request No. 5. While CMS interacts with and supports law enforcement, the agency does not serve a criminal law enforcement function and, therefore, it does not create or retain Reports of Investigation (ROIs) memorializing government communications with witnesses.

Given the October 2nd deadline for document production contained in the Court's July 19, 2019 Order, CMS had limited time to review the potentially responsive documents before production. As a result, non-responsive, privileged, or otherwise protected information, including deliberative internal communications that are not about Theranos, may be included in the CMS productions to the parties. The production to the United States, Holmes, and/or Balwani of non-responsive, privileged, or otherwise protected information in CMS's documents, including but not limited to deliberative internal communications that are not about Theranos contained in such documents, whether knowing or inadvertent, will not be considered a waiver of any privileges or protections that CMS may have with regard to such documents or information.

Please contact CMS counsel Lindsay Turner if there is a need to discuss this matter further.

Sincerely,



Karen W. Dyer
Director
Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services